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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,715	06/18/2001	Mark Pines	CGD-004.0P-U	7532

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EXAMINER
KWON, BRIAN YONG S

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 01/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/762,715	PINES ET AL.	
	Examiner	Art Unit	
	Brian S Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,18,20,21 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17,18,20,21 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of Application

By amendment filed October 07, 2002, Claims 1-16, 19 and 22 have been cancelled. Claims 17-18, 20-21 and 23 are currently pending.

Summary of Action

I. The rejection of claims 21 and 23 under 35 USC 112, second paragraph, will be maintained for the reason of the record.

II. The rejection of claims 17-18, 20-21 and 23 under the judicially created doctrine of double patenting will be maintained for the reason of the record.

III. The rejection of claims 17-18, 20-21 and 23 under 35 USC 102(b) will be maintained for the reason of the record.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is analogous to the original rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-18, 20-21 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Pines et al. (US 5449678 A).

This rejection is analogous to the original rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 17-18, 20-21 and 23 are rejected under the judicially created doctrine of double patenting over claim 1 of U. S. Patent No. 5,449,678 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

This rejection is analogous to the original rejection.

Response to Arguments

Applicant's arguments filed October 07, 2002 have been fully considered but they are not persuasive.

Applicants argument takes position that the term "substantially prevent" refers to any types of prevention of cardiac fibrosis, regardless of whether absolute and complete prevention is

achieved. Applicants alleges that since Halofuginone was shown in the instant specification to be clearly effective for preventing cardiac fibrosis, even if absolute and complete inhibition of all molecular processes contributing toward cardiac fibrosis was not shown, the term "substantially preventing" is definite. The Examiner disagrees.

The instant specification reveals no standard of measure of degree for such term in the claim. The specification is silent as to whether the fibrotic condition (e.g., CVF) is still existed or not after the administration of Halofuginone. Furthermore, the specification (page 26, line 21 thru page 27, line 2) does not support the instant scope of preventing the occurrence of cardiac fibrosis from ever happening. Applicants rely upon Example 5 (especially Figure 6) for meaning "any type of prevention of cardiac fibrosis" including "absolute and complete prevention". However, Figure 6 fails to show "absolute and complete prevention". Rather, Figure 6 only supports the effect of Halofuginone in treating cardiac fibrosis. Since the scope of the instant claims is subject to the interpretation of (i) "absolute and complete prevention" or "a partial inhibition", the term "substantially preventing" leaves doubt as to which subject matter which applicant regards as the invention. In view of the differences of the scope of protection which may be attached to the various categories of claims, it must be ensured that wording to a claim leaves no doubt as to its category.

Applicants argument takes position that Pines' 678 does not disclose the specific features of the currently claimed invention. Applicants alleges that (i) the present application does not rely solely upon collagen type I synthesis inhibiting mechanism of Halofuginone, as disclosed and taught in the present application; (ii) the illustrative examples in Pines'678 which describes

in vitro tissue culture experiments to determine the effect of Halofuginone on skin fibroblasts and chondrocytes is in no way predictive of any effect of Halofuginone in vivo or vitro treatment for fibrotic myocardial tissue, since cardiac tissues are different from other types of tissues. These are spurious arguments.

As evidenced by Example 5, especially Page 25, lines 5-11 of the instant specification, applicants clearly admit that Halofuginone is able to prevent cardiac fibrosis by inhibiting the deposition of type I collagen, as disclosed and taught in Pines' 678. In other words, regardless of absence of teaching in the involvement of extracellular matrix components in Pines' 678, the prior art clearly teaches that the anti-fibrotic and collagen type I synthesis inhibitory activity of Halofuginone is useful in the treatment of cardiac fibrosis, namely myocardial fibrosis. Furthermore, regardless of different cell types involved in cardiac fibrosis, one having ordinary skill in the art must know that cardiac fibrosis can be treated through inhibition of collagen type I synthesis. The Examiner maintains that the prior art clearly teaches the use of antifibrotic drug such as Halofuginone for treating a fibrotic condition such as cardiac fibrosis by inhibiting the deposition of type I collagen, regardless of the tissue types.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703)308-5377. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1600

Zohreh Fay